PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Dementia-friendly interventions to improve the care of people living with dementia admitted to hospitals: a realist review
AUTHORS	Handley, Melanie; Bunn, Frances; Goodman, Claire

VERSION 1 - REVIEW

REVIEWER	Sonia Dalkin
	Northumbria University, UK
REVIEW RETURNED	12-Dec-2016

GENERAL COMMENTS	The paper is very well written and provides an important synthesis of the literature surrounding dementia friendly interventions and environments in secondary care. The study design is appropriate and the findings are discussed in detail. I have very few comments, apart from those detailed below:
	Pg. 6, line 23. Could the authors address whether there is a missing word in this sentence? Or it may need rephrasing: "Credible evidence informed hypotheses in the form of 'If then statements' were used to set out the conditions thought to be necessary for outcomes to be achieved."
	Pg. 7, line 42. Could the authors provide more details on how bias was avoided if MH screened all papers and performed data extraction? Often this role is carried out by two researchers and discrepancies are adjudicated by a third researcher. What was the justification for MH doing this role alone?
	Pg. 7, line 55. Is it possible to share your data extraction form as a supplementary file? This isn't a necessity but may assist the reader in understanding how the data was extracted, thus aiding in transparency.
	Pg. 9, line 38. Typo - 'priorities' in table 1.
	Pg. 10, line 10. Table 2 is clear and succinct – a great way to combine evidence and detail initial programme theories. This is very transparent; a great credit to the paper.
	Pg. 11, Line 47 (also in the abstract). Were the 28 papers included in the synthesis in phase two additional to the 22 papers used in phase one?
	Pg. 12, Table 3. Table 3 describes well formed CMOs. It seems that the authors have often placed the mechanism resource within the context, which is methodologically sound. However, sometimes this can lead to confusion between context and resource. The authors

may wish to consider clarifying this.

Resources are very well described in the text accompanying the table (e.g. "training in dementia [10, 15, 53, 57, 60]; the use of biographical tools, completed in partnership with informal carers, [38, 51, 65, 68, 72]; assessments of cognition, pain, and psychological needs [48, 52, 58, 73]; and access to experts in dementia care [38, 40, 43, 48, 52, 68]. These resources reportedly supported the development of individualised care plans [43, 65] and personalised strategies for reducing distress [37, 68]." It would be useful to further distil what it is about these resources that evoke a response from stakeholders (if possible). What do these resources have in common? This might further enhance the utility of the findings to practice based and academic readers. By doing this, the findings are further synthesised and become more useful to both practice partners and academics.

Pg. 18, Line 19. The authors provide "a number of important components for the provision of dementia friendly health care" in the "Refined Theory" section. However, this section doesn't seem to fit with the realist logic of analysis. There are no explicit contexts, mechanisms or outcomes outlined. The paper seems to lose sight of the realist methodology in this section. Furthermore, it could lead to a misunderstanding; the reader could think that the CMO configurations described in the findings section are not programme theories (CMO configurations are in themselves refined programme theories as they describe if, how and in which circumstances an intervention works). I think this section would benefit from further analysis to a) make it more realist and b) to build an overall programme theory which encapsulates all of the (smaller) programme theories (CMOs) described in the findings section (if possible). This overall programme theory would be the take away message: In which context, and through which mechanisms do interventions lead to positive outcomes? This would then meet the RAMESES quality standards for understanding and applying the underpinning principles of a realist review at the highest level ('excellent').

Page 20, line 2. Typo – "Staff will still a need to work as a team, rather than creating new tasks to focus on."

Line 26. Related to the above comment ref pg. 18. The authors state that "The programme theory that has emerged from this review has the potential to improve how interventions to support dementia friendly care in hospitals are designed and evaluated". However, the reader may be unsure which programme theory you are referring to (CMO 1, 2, 3, 4, or 5 in the findings section?) as an overall, summary programme theory is not currently clearly stated.

In summary, this is a very engaging paper with interesting and novel findings. The comments provided have the intention to enhance, as opposed to critique.

REVIEWER	Chrysanthi Papoutsi
	University of Oxford, UK
REVIEW RETURNED	14-Dec-2016

GENERAL COMMENTS

I read this realist review on dementia-friendly interventions with great interest. The paper presents a clear, well-written and insightful analysis of the literature on factors that play a role in making secondary care more suitable for people living with dementia.

My comments mainly relate to the way the realist approach is used in this review:

- I was wondering if the paper could include a glossary for terms such as contexts, mechanisms, outcomes and a definition for configurations. This may help readers who are unfamiliar with the approach.
- I was interested to see eligibility for inclusion was assessed on the basis of whether the paper reported patient outcomes or reported on a specific intervention. It would be good to discuss what impact this decision had on the resulting set of papers and whether information in excluded papers could have been useful to further refine and substantiate CMOCs. It is also a little unclear what is meant by patient outcomes or interventions (is it about the articles framing 'patient outcomes' or 'interventions' as such, or is this sometimes a matter of interpretation?). The paper mentions a second search took place but this is not clearly illustrated in the flow diagram (Figure 1). Were the additional searches run in parallel with the main search, rather than iteratively were the inclusion/exclusion criteria the same?
- It may also be worth adding some more detail about the characteristics of the studies included in the review, e.g. quantitative/qualitative studies (or reference to a full report, e.g. PhD thesis, if this is available online).
- The paper could include some more explanation on why a realist review was appropriate to study this topic (e.g. because of complexity?) and it would be useful to add the review questions as part of the methods section (see RAMESES publication standards).
- It may also be useful to explain how the analytical process moved from framework analysis towards developing explanatory CMOCs.

- In the findings section, phase 1, paragraph 1, the description of stakeholders could be moved to methods. Given the interviews were treated as primary data collection (specific analysis performed on the data and quotes included in the paper), it may be worth explaining sampling (e.g. purposive?) and what happened during the interviews (questions asked, consent, transcription etc.). Did the stakeholders have any more involvement, e.g. providing feedback and shaping the CMOCs and resulting programme theory?
- One of the main things the paper needs to address is the configuration, framing and presentation of CMOCs in table 3 (as much as this can become self-explanatory without the narrative text in the results section).
 - Outcomes: I am wondering if the analysis would benefit from identifying some intermediate outcomes, rather than directing all CMOCs towards patient/health outcomes or other big concepts such as patient safety. It is difficult to understand what is meant by these big concepts and what exactly the outcome has been. This may require further interpretation of the articles reviewed to understand what are the intermediate steps that lead (or not) to these big outcomes. Particularly CMOC6 seems to be making big jumps between the different concepts mentioned.
 - Mechanisms: This relates to the previous point, as it looks like some mechanisms (e.g. CMOC1 'will prioritise addressing the cause of behaviour...') sound more like outcomes (they are observable behaviours whereas mechanisms are hidden reasoning processes)? What is it about an environment that supports staff to understand and properly interpret behaviours that challenge (context) that generates certain responses in people, e.g. could it be they are feeling more empathy as mentioned in a different point in the paper? Making inferences from the data in the

included papers could help refine the concepts identified as mechanisms in the CMOCs. It may just be about framing the CMOC in a different way rather full revision.

- I would suggest elaborating a little more on what the strengths of the review were. The limitations could also be a little more specific, e.g. for which CMOCs did the authors have less data and how would you propose future research could address this 'gap'?
- The paper mentions that the first stage of the review focused on theory building and the literature retrieved was used for theory 'testing'. I am wondering if limited data and lack of comprehensive evaluations means this paper is primarily theory building and there could be a follow-up (e.g. an evaluation?) to aid theory 'testing'?
- I would also avoid using the word 'anecdotal' perhaps say the literature suggests X and more work is need to understand how it works in practice?
- Has the review been registered with PROSPERO? Is there a reporting checklist, e.g. RAMESES publication standards in the full report for this study?

There a few small typos which I have highlighted on the pdf (uploaded on the system). I hope the authors find the comments helpful in revising the paper.

The reviewer also provided a marked copy with additional comments. Please contact the publisher for full details.

REVIEWER	Justin Jagosh University of Liverpool
	United Kingdom
REVIEW RETURNED	23-Dec-2016

GENERAL COMMENTS	This is a well written manuscript on an important topic. The authors have grasped the fundamentals of realist methodology and have, in my opinion, satisfied the quality requirements for the approach. The follow are a few minor recommendations to improve the manuscript:
	Please add a small section on realist methodology. I suspect the authors have already done this in the protocol paper but it would

serve this paper well to have a paragraph description of the methodology, including a short table providing a definition of terms for C, M, and O and programme theory as it has been tailored to the needs of this study

- 2. The authors may wish to scrutinize their paper against the RAMESES I reporting guidelines for realist synthesis and if it meets those criteria, to include "that the review has been vetted against RAMESES criteria" for help the novice reader feel increased confidence in taking up the findings
- 3. A visual model or framework that brings together the different components/mechanisms may help the reader to more quickly understand the findings.
- 4. The section on 'Refined Theory' is well placed, but could be developed further and clarified. The section could more clearly highlight what was missing from the initial theory development now that the CMOc analysis has revealed more detail about how the Dementia-friendly interventions work. A table contrasting the initial vs. refined theory could be considered if the authors felt that would make sense.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Pg. 6, line 23. Could the authors address whether there is a missing word in this sentence? Or it may need rephrasing: "Credible evidence informed hypotheses in the form of 'If... then statements' were used to set out the conditions thought to be necessary for outcomes to be achieved."

• This has been amended to address subsequent comments (page 7)

Pg. 7, line 42. Could the authors provide more details on how bias was avoided if MH screened all papers and performed data extraction? Often this role is carried out by two researchers and discrepancies are adjudicated by a third researcher. What was the justification for MH doing this role alone?

- The following text has been added: The data extraction form was piloted by MH and shared with the team for comments and modifications [supplementary file 3]. To reduce the potential for bias during data extraction, a sample of the papers and their completed data extraction forms (6/28) were shared with FB and CG to appraise the extraction process and identified data. Information about the role and work of the change agent, the resources provided by the interventions, the contextual features of the settings (e.g. workforce, knowledge of dementia), explicit and implicit theories for how interventions were anticipated to work, and patient and carer outcomes were extracted. Coded data from all the papers and the relevant contribution to theory development were further refined after discussion with FB and CG, (page 9)
- Pg. 7, line 55. Is it possible to share your data extraction form as a supplementary file? This isn't a necessity but may assist the reader in understanding how the data was extracted, thus aiding in transparency.

• Yes, this is now included as supplementary file 3.

Pg. 9, line 38. Typo - 'priorities' in table 1.

- Amended to prioritises (page 11)
- Pg. 10, line 10. Table 2 is clear and succinct a great way to combine evidence and detail initial programme theories. This is very transparent; a great credit to the paper.
- Thank you
- Pg. 11, Line 47 (also in the abstract). Were the 28 papers included in the synthesis in phase two additional to the 22 papers used in phase one?
- Highlighted words added for clarification: Evidence from 28 papers, 12 of which had been identified and included in phase one of the review, led to the development of six context-mechanism-outcome configurations (CMOs) that tested the components of the three theoretical propositions developed in phase one (an overview of the selection process can be seen in Figure 1). (page 13)
- Pg. 12, Table 3. Table 3 describes well formed CMOs. It seems that the authors have often placed the mechanism resource within the context, which is methodologically sound. However, sometimes this can lead to confusion between context and resource. The authors may wish to consider clarifying this.
- The table has now been amended and also addresses comments from reviewer 2 (page 14). Mechanisms have now been split by resources and reasoning and defined in the glossary of terms (box 2, page 10).

Resources are very well described in the text accompanying the table (e.g. "training in dementia [10, 15, 53, 57, 60]; the use of biographical tools, completed in partnership with informal carers, [38, 51, 65, 68, 72]; assessments of cognition, pain, and psychological needs [48, 52, 58, 73]; and access to experts in dementia care [38, 40, 43, 48, 52, 68]. These resources reportedly supported the development of individualised care plans [43, 65] and personalised strategies for reducing distress [37, 68]." It would be useful to further distil what it is about these resources that evoke a response from stakeholders (if possible). What do these resources have in common? This might further enhance the utility of the findings to practice based and academic readers. By doing this, the findings are further synthesised and become more useful to both practice partners and academics.

- Text has been amended to read: Common to these interventions were that they supported staff to consider potential causes of behaviours and provided strategies to address the unmet need, such as the development of individualised care plans [44, 66] and personalised strategies for reducing distress [38, 69]. (page 16)
- Pg. 18, Line 19. The authors provide "a number of important components for the provision of dementia friendly health care" in the "Refined Theory" section. However, this section doesn't seem to fit with the realist logic of analysis. There are no explicit contexts, mechanisms or outcomes outlined. The paper seems to lose sight of the realist methodology in this section. Furthermore, it could lead to a misunderstanding; the reader could think that the CMO configurations described in the findings section are not programme theories (CMO configurations are in themselves refined programme theories as they describe if, how and in which circumstances an intervention works). I think this section would benefit from further analysis to a) make it more realist and b) to build an overall programme theory which encapsulates all of the (smaller) programme theories (CMOs) described in the findings section (if possible). This overall programme theory would be the take away message: In which context, and through which mechanisms do interventions lead to positive outcomes? This would then meet the RAMESES quality standards for understanding and applying the underpinning

principles of a realist review at the highest level ('excellent').

• This section has now been amended to explicitly set out the context, mechanisms and outcomes and address comments raised by other reviewers (page 20).

Page 20, line 2. Typo – "Staff will still a need to work as a team, rather than creating new tasks to focus on."

• Amended to: Staff will still need to work as a team, rather than creating new tasks to focus on. (page 22)

Line 26. Related to the above comment ref pg. 18. The authors state that "The programme theory that has emerged from this review has the potential to improve how interventions to support dementia friendly care in hospitals are designed and evaluated". However, the reader may be unsure which programme theory you are referring to (CMO 1, 2, 3, 4, or 5 in the findings section?) as an overall, summary programme theory is not currently clearly stated.

• The title of 'refined theory' has been amended to read 'Refined Programme Theory' and reference is made to the 6 CMOCs building the programme theory. (page 20)

In summary, this is a very engaging paper with interesting and novel findings. The comments provided have the intention to enhance, as opposed to critique.

Reviewer: 2

My comments mainly relate to the way the realist approach is used in this review:

- I was wondering if the paper could include a glossary for terms such as contexts, mechanisms, outcomes and a definition for configurations. This may help readers who are unfamiliar with the approach.
- A glossary of terms has been included as Box 2 (page 10)

I was interested to see eligibility for inclusion was assessed on the basis of whether the paper reported patient outcomes or reported on a specific intervention. It would be good to discuss what impact this decision had on the resulting set of papers and whether information in excluded papers could have been useful to further refine and substantiate CMOCs.

• The follow text has been added: Our review also highlights the importance of focusing on patient related outcomes. It was clear from the initial interviews that whilst there was a shared understanding of the importance of dementia friendly care, less attention has been paid to how different approaches enhanced patient outcomes. By focusing on outcomes as the basis for inclusion, this review addresses a knowledge gap about how different resources and approaches for dementia friendly healthcare are effective for patients. (page 23)

It is also a little unclear what is meant by patient outcomes or interventions (is it about the articles framing 'patient outcomes' or 'interventions' as such, or is this sometimes a matter of interpretation?).

Patient outcomes have been defined in the glossary of realist terms (Box 2, page 10)

The paper mentions a second search took place but this is not clearly illustrated in the flow diagram (Figure 1).

• An additional box has been added to the figure to indicate the separate search and amended text has been highlighted. (Figure 1)

Were the additional searches run in parallel with the main search, rather than iteratively – were the inclusion/exclusion criteria the same?

- Text has been amended to read: Additional searches were performed as emerging themes around the management of pain and behaviours that challenge became apparent. These were purposive searches that applied the same inclusion criteria and supported theory development until theoretical saturation was achieved [36, 37] (box 1). (page 7)
- In additional, additional text has been added to Box 1: Additional search terms from emerging themes during phase two run January 2016, search alerts scanned to February 2016 (page 8)

It may also be worth adding some more detail about the characteristics of the studies included in the review, e.g. quantitative/qualitative studies (or reference to a full report, e.g. PhD thesis, if this is available online).

• The characteristics of the studies are now included in Supplementary file 5 (reference added in text)

The paper could include some more explanation on why a realist review was appropriate to study this topic (e.g. because of complexity?) and it would be useful to add the review questions as part of the methods section (see RAMESES publication standards).

- Text has been amended before the methods section to include: The review objectives were:
- 1. To identify how dementia friendly interventions in hospital settings are thought to achieve the desired patient and carer outcomes
- 2. To develop evidence-based explanations to understand what it is about dementia friendly interventions used in hospitals that works for people living with dementia and their carers, in what circumstances and why.

Realist Methodology

Realist review is a theory-led method, that applies the principles of realist theory to evidence review [31]. In realism, causation is considered as generative rather than linear and does not consider that the introduction of an intervention leads directly to change. Instead, a realist approach seeks to explain how the relationship between the resources an intervention introduces and the context it is implemented into influences peoples' reasoning for taking action and generating change [31].

Realist review was appropriate for this study for a number of reasons. The evidence base for dementia friendly interventions is in its early stages. These interventions are complex in both design and implementation; they are multicomponent and rely on human agency that is influenced by individual, service and organisational pressures. Instead of seeing these as confounding factors, realist inquiry acknowledges these features and incorporates them to develop an explanatory account of how different aspects influence reasoning and outcomes [32]. (page 7)

It may also be useful to explain how the analytical process moved from framework analysis towards developing explanatory CMOCs.

• More detail has been added to this section to further detail the research process: Data from interviews and the literature were coded using framework analysis [34] with emerging themes and competing accounts discussed and debated amongst the authors (MH, FB, CG) and with Alzheimer's Society research network monitors (RP, JW, PM) who were volunteer representatives with experience of caring for family members living with dementia. Mapping of this evidence, also shared with the team, demonstrated limited understanding at the point of staff interaction with patients and how this effected patient outcomes. A decision was made to focus the review on how interventions led to patient outcomes. Data from the interviews and literature were scrutinised for demi-regularities (see glossary of realist terms) and informed hypotheses set out in the form of 'If... then statements'. These statements were used to define the conditions thought to be necessary to achieve: 1) staff outcomes, such as taking action to investigate the cause of patient behaviours and applying best practice with people living with dementia; and 2) patient outcomes, such as reduced distress, reduction in adverse incidents, and improved wellbeing. Discussions amongst the authors based on the statements led to the development of a conceptual framework [31]. Three overlapping theoretical propositions were generated to explain what supports the implementation and uptake of interventions that promote dementia friendly health care within a ward based environment. (page 7)

In the findings section, phase 1, paragraph 1, the description of stakeholders could be moved to methods. Given the interviews were treated as primary data collection (specific analysis performed on the data and quotes included in the paper), it may be worth explaining sampling (e.g. purposive?) and what happened during the interviews (questions asked, consent, transcription etc.). Did the stakeholders have any more involvement, e.g. providing feedback and shaping the CMOCs and resulting programme theory?

- Text has been moved to the methods section and amended as follows:
- They were purposively sampled from a range of settings (academia, health care, commissioning, social work, the community) and backgrounds (nursing, education, physiotherapy, research, person living with dementia) [33]. Stakeholders were not further involved in the development of the emerging CMOCs or programme theory. (page 6-7)
- An amendment was made to the paper to highlight a change in the review process from the published protocol:

Changes to the review process

One change to the review process was made subsequent to the published review protocol [33]. The expert steering group workshop was not held. However, emerging findings and the refined programme theory were shared with the with Alzheimer's Society research network monitors (RP, JW, PM) who were volunteer representatives with experience of caring for family members living with dementia. They commented on the resonance and relevance of the inferences that contributed to the developing theory throughout the review process. Review findings were also presented and discussed at a seminar on dementia friendly health care with 75 participants, 19 of whom worked in hospitals. The findings are being taken forward for testing in a realist evaluation. (page 5)

One of the main things the paper needs to address is the configuration, framing and presentation of CMOCs in table 3 (as much as this can become self-explanatory without the narrative text in the results section).

- o Outcomes: I am wondering if the analysis would benefit from identifying some intermediate outcomes, rather than directing all CMOCs towards patient/health outcomes or other big concepts such as patient safety. It is difficult to understand what is meant by these big concepts and what exactly the outcome has been. This may require further interpretation of the articles reviewed to understand what are the intermediate steps that lead (or not) to these big outcomes. Particularly CMOC6 seems to be making big jumps between the different concepts mentioned.
- The table has been amended to reflect the above comment and focus the outcomes to staff outcomes or actions, such as the adoption of care practices that consider the difficulties a person with dementia faces, rather than directing the CMOCs to patient outcomes. Amendments have been highlighted. (page 14-15)

o Mechanisms: This relates to the previous point, as it looks like some mechanisms (e.g. CMOC1 'will prioritise addressing the cause of behaviour...') sound more like outcomes (they are observable behaviours whereas mechanisms are hidden reasoning processes)? What is it about an environment that supports staff to understand and properly interpret behaviours that challenge (context) that generates certain responses in people, e.g. could it be they are feeling more empathy as mentioned in a different point in the paper? Making inferences from the data in the included papers could help refine the concepts identified as mechanisms in the CMOCs. It may just be about framing the CMOC in a different way rather full revision.

• Revisions have been made to the CMOCs to reflect this by amending mechanisms to outcomes where appropriate, such as respond appropriately to meet the person's individual needs (outcome). Changes to the table are highlighted throughout the table. (page 14-15)

I would suggest elaborating a little more on what the strengths of the review were. The limitations could also be a little more specific, e.g. for which CMOCs did the authors have less data and how would you propose future research could address this 'gap'?

- The strengths of the review have been developed and the following text has been added: This review does, however, provide a programme theory that can be used as the basis for future evaluations. Our review also highlights the importance of focusing on patient related outcomes. It was clear from the initial interviews that whilst there was a shared understanding of the importance of dementia friendly care, less attention has been paid to how different approaches enhanced patient outcomes. By focusing on outcomes as the basis for inclusion, this review addresses a knowledge gap about how different resources and approaches for dementia friendly healthcare are effective for patients. (page 23)
- Limitations have are now more specific: Available evidence clustered around the training for staff and organisational support for changes to care practices. There was less evidence for how the introduction of staff providing activity and therapy for people living with dementia impacted on the practices of other staff. (page 23)

The paper mentions that the first stage of the review focused on theory building and the literature retrieved was used for theory 'testing'. I am wondering if limited data and lack of comprehensive evaluations means this paper is primarily theory building and there could be a follow-up (e.g. an evaluation?) to aid theory 'testing'?

- Acknowledged and amended where necessary.
- Additional text added: The initial aim of the review was to develop, test and refine a programme theory for how dementia friendly interventions influence outcomes for people living with dementia during hospital admissions. However, testing the theory was problematic as evidence was limited, much was descriptive, there were few evaluations of interventions and approaches, and limited descriptions of setting and component parts of the interventions which impacted on the development of CMO configurations... This review does, however, provide a programme theory that can be used as the basis for future evaluations. (page 22-23)

I would also avoid using the word 'anecdotal' – perhaps say the literature suggests X and more work is need to understand how it works in practice?

· Amended and highlighted throughout.

Has the review been registered with PROSPERO? Is there a reporting checklist, e.g. RAMESES publication standards in the full report for this study?

• Yes, reference to PROSPERO in abstract (page 2)

A checklist for RAMESES publication standards has been included as Supplementary files 1 and 2

There a few small typos which I have highlighted on the pdf (uploaded on the system). I hope the authors find the comments helpful in revising the paper

• Thank you, amended and highlighted throughout

Reviewer: 3

- 1. Please add a small section on realist methodology. I suspect the authors have already done this in the protocol paper but it would serve this paper well to have a paragraph description of the methodology, including a short table providing a definition of terms for C, M, and O and programme theory as it has been tailored to the needs of this study
- A section on realist methodology has been added (page 5)
- 2. The authors may wish to scrutinize their paper against the RAMESES I reporting guidelines for realist synthesis and if it meets those criteria, to include "that the review has been vetted against RAMESES criteria" for help the novice reader feel increased confidence in taking up the findings
- The authors have reviewed the paper against the RAMESES criteria and consider that it meets the reporting standards. The suggested text has been added (page 6)
- 3. A visual model or framework that brings together the different components/mechanisms may help the reader to more quickly understand the findings.
- A diagram has been included that is in-line with previous BMJ Open realist publications
- 4. The section on 'Refined Theory' is well placed, but could be developed further and clarified. The section could more clearly highlight what was missing from the initial theory development now that the CMOc analysis has revealed more detail about how the Dementia-friendly interventions work. A table contrasting the initial vs. refined theory could be considered if the authors felt that would make sense.
- Text has been amended to highlight where the work in phase two developed the initial theories from phase one and a more detailed development of the programme theory has been included to explicitly lay out the context, mechanisms and outcomes. (page 20-21)
- The authors consider that these amendments to the Refined Programme Theory section clarify the theory development.

I would like to thank the reviewers for their comments which have helped to refine the paper. I look forward to your hearing your decision on the manuscript.

VERSION 2 - REVIEW

REVIEWER	Sonia Dalkin
	Northumbria University, UK
REVIEW RETURNED	17-Feb-2017

GENERAL COMMENTS	The authors have addressed all of the concerns from my initial review. However, there are a few additional issues as a result of the edit:
	The definition of context provided in Box 2 could be improved (pg.79). There is also a typo in the context-mechanism-outcome configuration definition.

There is no mechanism resource in the following two CMOc (pg.83/84):

- "Staff with flexibility in their role and working environment (context), will use their professional judgement (mechanism reasoning) to provide care and treatment to a person in a timely manner (outcome), and will support patients in a person-centred way that is responsive to their needs (outcome)."
- "Staff who understand the procedures and expectations for care that address

risk in a person-centred way (context), and are confident that they are

supported by organisation (mechanism reasoning) will address risk proportionately (outcome)"

Consider removing 'intervention' from mechanism resource box in Figure 2. This could suggest that you are conflating resource and intervention. Instead consider, for example, in preliminary CMO: "Promotion of good dementia care and support to increase dementia awareness"

Also in Figure 2, in the intermediate CMO, reasoning box, it would be helpful to add that this is the staff's reasoning.

Pg. 89 I think Figure 2 would benefit from a narrative to explain it a little more - the reader might not readily understand what a preliminary CMO is and you don't refer to this anywhere else in the article. Is the resource the same or different in the preliminary and the intermediate CMOc (either could be fine, but requires explanation). Why is it an 'anticipated' outcome and not just an outcome? Is this a hypothesised outcome? Is this because there was little evidence, or outside the scope of your review? A short paragraph would really help the reader to engage with this diagram and understand it thoroughly.

Typos and phrasing need to be addressed throughout.

I think this is a paper that should be published, it just now needs fine tuning by the authors. I hope my comments help the authors to do this.

REVIEWER	Chrysanthi Papoutsi
	University of Oxford, UK
REVIEW RETURNED	02-Mar-2017

GENERAL COMMENTS	The authors have made a great effort in revising the paper and most points have been fully addressed. There is still some scope to refine the CMOCs to reach a more explanatory level of analysis. Also, some of the negative aspects of the CMOCs described in the Phase 2 section are not reflected in the CMOC table 3. Someone referring to the table (where CMOCs are framed in very definitive language e.g. staff will) without looking at the analysis may not understand the nuances of the arguments made. I am wondering if some of these CMOCs could be made more explicit about legitimacy, clarifying expectations and staff being able to feel in control (all mentioned throughout the text in various ways, but could be highlighted more - although I am not familiar with the data so may be making wrong interpretations here). For example CMOC1 makes me think that, in environments where behaviours

that challenge are perceived as expression of unmet need (context), staff members may feel this gives them an option to be in control as there is something they can do about the situation (mechanism), which in turn may make it more likely that they will try to identify and address the unmet need (outcome)? However, this may not happen if the working environment does not see this work as legitimate (context), as staff will feel that this is not what is expected of their role (mechanism), and they will be less likely to spend this additional time needed with patients (outcome) - as described in last paragraph under subheading 'CMO 2. The role of experiential learning, creating empathy and how it encourages reflection'. Or in relation to CMO3: 'Staff with flexibility in their role and working environment (context), will use their professional judgement (mechanism reasoning) to provide care and treatment to a person in a timely manner (outcome), and will support patients in a personcentred way that is responsive to their needs (outcome).' Again, what is it about 'flexibility' that makes people behave in a certain way? Is it that they feel it is a legitimate part of their work to prioritise psychosocial support and they are trying to fit in with what is expected of their professional role perhaps? And what does 'professional judgment' mean? Would it be about feeling responsible to make decisions that will make a difference for someone else? The above are just suggestions in case useful when revising the CMOCs, but they are not based on the data that the authors have, so may be misguided. The point I want to make is that the level of analysis may need to cover a higher level of abstraction. This will also help with transferability of findings.

It may also be useful to include one or two quotes that support each of the CMOCs, either in the text or as an appendix. I notice supplementary file 3 only includes extracted quotes for 'Evidence for theory area 1' which I believe is the preliminary analysis for initial theoretical assumptions.

It would be worth revising for typos.

Since a lot of the review is about workforce skills, the following could be useful:

https://www.ncbi.nlm.nih.gov/books/NBK355884/

I hope the authors find the comments helpful in their final revisions of the paper.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

The authors have addressed all of the concerns from my initial review. However, there are a few additional issues as a result of the edit:

The definition of context provided in Box 2 could be improved (pg.79). There is also a typo in the context-mechanism-outcome configuration definition.

Definition and typo amended (page 6)

There is no mechanism resource in the following two CMOc (pg.83/84):

- "Staff with flexibility in their role and working environment (context), will use their professional judgement (mechanism reasoning) to provide care and treatment to a person in a timely manner (outcome), and will support patients in a person-centred way that is responsive to their needs (outcome)."
- "Staff who understand the procedures and expectations for care that address risk in a person-

centred way (context), and are confident that they are supported by organisation (mechanism reasoning) will address risk proportionately (outcome)"

• The CMOcs in table 3 have been amended to reflect this comment and comments from Reviewer 2 (pages 15 – 18)

Consider removing 'intervention' from mechanism resource box in Figure 2. This could suggest that you are conflating resource and intervention. Instead consider, for example, in preliminary CMO: "Promotion of good dementia care and support to increase dementia awareness"

• Figure 2 has been amended

Also in Figure 2, in the intermediate CMO, reasoning box, it would be helpful to add that this is the staff's reasoning.

• Figure 2 has been amended

Pg. 89 I think Figure 2 would benefit from a narrative to explain it a little more - the reader might not readily understand what a preliminary CMO is and you don't refer to this anywhere else in the article. Is the resource the same or different in the preliminary and the intermediate CMOc (either could be fine, but requires explanation). Why is it an 'anticipated' outcome and not just an outcome? Is this a hypothesised outcome? Is this because there was little evidence, or outside the scope of your review? A short paragraph would really help the reader to engage with this diagram and understand it thoroughly.

• Narrative explanation added and highlighted in text (pages 23 – 24):

Figure 2 presents the programme theory. The preliminary CMOC suggests that resources which promote dementia awareness and an understanding of what constitutes 'good' dementia care are often initially implemented in situations where staff have limited understanding of how to provide care that addresses the needs of people living with dementia. These resources support staff to recognise the benefit of working well with patients with dementia and provides them with a common understanding of what good care looks like. This preliminary outcome then becomes part of the new context. Contextual factors, such as organisational endorsement of dementia care practices and clarity in staff responsibilities to patients with dementia, encourage staff to value resources, reinforcing improvements to care provision. It is anticipated that this will lead to improved patient outcomes, though evidence on outcomes was limited.

Typos and phrasing need to be addressed throughout.

• Amendments for typos and phrasing highlighted throughout.

I think this is a paper that should be published, it just now needs fine tuning by the authors. I hope my comments help the authors to do this.

Reviewer: 2

The authors have made a great effort in revising the paper and most points have been fully addressed. There is still some scope to refine the CMOCs to reach a more explanatory level of analysis.

Also, some of the negative aspects of the CMOCs described in the Phase 2 section are not reflected in the CMOC table 3. Someone referring to the table (where CMOCs are framed in very definitive language e.g. staff will...) without looking at the analysis may not understand the nuances of the

arguments made.

• Language has been amended in the table to reflect the nuances discussed in the CMOC evidence (pages 15 - 18).

I am wondering if some of these CMOCs could be made more explicit about legitimacy, clarifying expectations and staff being able to feel in control (all mentioned throughout the text in various ways, but could be highlighted more - although I am not familiar with the data so may be making wrong interpretations here). For example CMOC1 makes me think that, in environments where behaviours that challenge are perceived as expression of unmet need (context), staff members may feel this gives them an option to be in control as there is something they can do about the situation (mechanism), which in turn may make it more likely that they will try to identify and address the unmet need (outcome)? However, this may not happen if the working environment does not see this work as legitimate (context), as staff will feel that this is not what is expected of their role (mechanism), and they will be less likely to spend this additional time needed with patients (outcome) – as described in last paragraph under subheading 'CMO 2. The role of experiential learning, creating empathy and how it encourages reflection'.

Or in relation to CMO3: 'Staff with flexibility in their role and working environment (context), will use their professional judgement (mechanism reasoning) to provide care and treatment to a person in a timely manner (outcome), and will support patients in a person-centred way that is responsive to their needs (outcome).' Again, what is it about 'flexibility' that makes people behave in a certain way? Is it that they feel it is a legitimate part of their work to prioritise psychosocial support and they are trying to fit in with what is expected of their professional role perhaps? And what does 'professional judgment' mean? Would it be about feeling responsible to make decisions that will make a difference for someone else?

The above are just suggestions in case useful when revising the CMOCs, but they are not based on the data that the authors have, so may be misguided. The point I want to make is that the level of analysis may need to cover a higher level of abstraction. This will also help with transferability of findings.

- Table 3 has been adapted to incorporate these changes (pages 15 18).
- \bullet Some revision of the CMOC text has been made and revisions are highlighted throughout (pages 19 -23)

It may also be useful to include one or two quotes that support each of the CMOCs, either in the text or as an appendix. I notice supplementary file 3 only includes extracted quotes for 'Evidence for theory area 1' which I believe is the preliminary analysis for initial theoretical assumptions.

• Supplementary file 6 added to include illustrative quotes that support each of the CMOCs.

I look forward to your hearing your decision on the manuscript.

VERSION 3 - REVIEW

REVIEWER	Sonia Dalkin
	Northumbria University, UK
REVIEW RETURNED	10-Apr-2017

GENERAL COMMENTS	The authors have made considerable revisions and addressed all of
	my concerns. An interesting and thought provoking paper.

REVIEWER	Chrysanthi Papoutsi

	University of Oxford, UK
REVIEW RETURNED	19-Apr-2017

GENERAL COMMENTS	The paper has been revised to address the majority of the comments. I have focused this review on Table 3 and the changes to the CMOCs. It was good to see how the authors have extracted data from the literature to support the CMOCs in supplementary file 6. This makes it easier to understand how the CMOCs were constructed and where the literature reviewed may/may not include enough data to allow inferences to be made with confidence.
	In the way the CMOCs are described in Table 3, there seems to be some conflating between interventions/context (e.g. CMOC2 'access to training'), interventions/mechanism resources (e.g. CMOC1 on 'training, resources and support from experts') and context/mechanism resources (e.g. CMOC3 'focusing the responsibility for dementia care in select staff'). If the literature does not contain enough data to be able to distinguish (often interventions are very thinly described in published papers) then it would be worth making this explicit and being clear about the limitations of the CMOCs (i.e. which building blocks are based on data/inferences from the data and where more research may be needed to understand what is going on).
	I still think the paper should be published, as the authors have done a tremendous amount of work and their findings are useful for policy and practice. From a methodological perspective, perhaps there could be a small caveat that further analysis is needed to reach detailed CMOCs and a coherent realist programme theory.

VERSION 3 – AUTHOR RESPONSE

Reviewer: 2

From a methodological perspective, perhaps there could be a small caveat that further analysis is needed to reach detailed CMOCs and a coherent realist programme theory.

• An additional sentence has been added to the limitations area of the discussion in recognition of this caveat:

With these considerations, it is recognised that the proposed CMOCs were constrained by the evidence that was available and the inferences that could be made from the data; further development is needed. (Page 25)

I look forward to your hearing your decision on the manuscript.